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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,687	03/21/2005	Marie-Christine Wolf	PA/4-32689A	4645

67283 7590 04/30/2008

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,687	WOLF ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,16 and 17* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-13), drawn to an oral dosage form comprising oxcarbazepine in the reply filed on 3/20/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement is therefore made FINAL.

2. Claims 16-17 are withdrawn from consideration.

3. Claims 1-13 are included in the prosecution.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 3/21/05 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement.

See attached copy of PTO-1449.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Katzhendler et al. (US 6,296,873).

The claimed invention is an oral, once a day, dosage form consisting of a tablet core and a coating wherein the core comprises oxcarbazepine, optionally, a filler, and at least one further excipient selected from the group comprising cellulose ethers, carboxyvinyl polymer of acrylic acid cross linked with alkyl ethers of sucrose, carboxyvinyl polymer of acrylic acid cross linked with alkyl ethers of pentaerythritol and polymethacrylates.

Regarding instant claim 1, it should be noted that the claim language "adapted to" is functional language. In order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. In re Fuller, 1929 C.D. 172; 388 O.G. 279.

Katzhendler teaches "a controlled and sustained release oral drug delivery system comprising carbamazepine or a carbamazepine derivative. Carbamazepine or the derivative thereof is formulated within a polymeric matrix, said matrix optionally further containing additional pharmaceutically acceptable constituents and additives. The polymer in the polymeric matrix permits carbamazepine or its derivative to be released from the matrix by zero-order release kinetics" (Col. 6, lines 21-29). Oxcarbazepine (10,11-dihydro-10-oxo-5H-dibenz/b,f/azepine-5-carboxamide) is disclosed as a carbamazepine derivative that is used as the pharmaceutically active agent in the drug delivery system (Col. 3, lines 57-63). The mono hydroxy derivative

(MHD) of oxcarbazepine (10,11-dihydro-10-hydroxy-5H-dibenz/b,f/azepine-5-carboxamide) is also disclosed (Col. 3, lines 64-65). The polymer component of the drug delivery system comprises at least one hydrophilic polymer (Col. 8, lines 23-26) such as hydrophilic cellulose derivatives (Col. 8, lines 41-43). Hydroxypropyl methylcellulose (HPMC) is disclosed as a preferred hydrophilic cellulose derivative (Col. 8, lines 52-54). "Polymers are mixed with drug in a weight ratio of polymer to drug from about 1:99% to about 99:1%, preferably from about 5:95% to about 90:10%, most preferably from about 10:90% to about 80:20%, depending on the viscosity grade of the polymer, on the tablet dimension and shape and on the desired release rate" (Col. 8, lines 30-35). The erodible tablet form of the drug/matrix is disclosed (Col. 9, lines 25-27). The ratio of "drug : polymer is varied depending on the size and shape of the tablet, on the drug amount and drug release rate, and depends also on the molecular weight and viscosity grade of the polymer ..." (Col. 9, lines 28-34). Katzhendler also teaches that the polymeric matrix of the drug delivery may also contain a hydrophobic polymer such as ethylcellulose and methacrylic acid derivatives (Col. 9, lines 45-52). "The hydrophobic polymer is added to the hydrophilic polymer in amount from about 0.1 to about 10%, preferably from about 1% to about 5%, of the total polymer. Ratios of hydrophilic to hydrophobic polymer are from about 99.9:0.1 to about 90:10, preferably from about 99:1 to about 95:5" (Col. 9, lines 63-65). Tablets that may be coated with pharmaceutically acceptable coatings are disclosed (Col. 10, lines 60-67). The carbamazepine derivative is delivered once a day (Col. 11, lines 31-32).

Regarding instant claims 2 and 13, since the oral dosage form comprising oxcarbazepine that is administered once a day is anticipated by Katzhendler, the release of the oxcarbazepine to produce constant MHD plasma levels over 24 hours is an inherent property of the dosage form and is therefore anticipated by Katzhendler.

Therefore, the limitations of claims 1-4, 6 and 13 are anticipated by the teachings of Katzhendler.

8. Claims 3-4 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourquin (US 5,695,782).

Bourquin teaches a tablet core comprising a dosage unit of oxcarbazepine (10,11-dihydro-10-oxo-5H-dibenzo[b,f]azepine-5-carboxamide). The cellulose ether hydroxypropyl methyl cellulose disclosed as a component in a hydrophilic, permeable inner layer and in a hydrophilic, permeable outer layer (Col. 4, line 64 to Col. 5, line 40, Example 1). Microcrystalline cellulose is disclosed as the filler (Col. 5, line 22).

Therefore, the limitations of claims 3-4 and 9 are anticipated by the teachings of Bourquin.

9. Claims 3-4 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlütermann (WO 98/35681).

Schlütermann teaches a tablet core with oxcarbazepine, microcrystalline cellulose (AVICEL PH 102) and hydroxypropyl methyl cellulose (Page 10, Example 1).

Therefore, the limitations of claims 3-4 and 9 are anticipated by the teachings of Schlütermann.

10. Claims 3-4 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lang (WO 01/32183).

Lang teaches a tablet core with oxcarbazepine, microcrystalline cellulose and hydroxypropyl methyl cellulose (Cellulose HPM 603) (Page 13, lines 1-3 and Example 1).

Therefore, the limitations of claims 3-4 and 9 are anticipated by the teachings of Lang.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 5, 7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katzhendler et al. (US 6,296,873).

The teaching of Katzhendler is stated above.

Katzhendler does not expressly teach the weight ratio of total HPMC to oxcarbazepine from about 1:10 to about 1:20 or the weight ratio of total ethyl cellulose to oxcarbazepine from about 1:10 to about 1:20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a sustained release tablet of oxcarbazepine with HPMC and ethyl cellulose, as suggested by Katzhendler, and modify the weight ratio of total HPMC to oxcarbazepine and the weight ratio of total ethyl cellulose to oxcarbazepine because during the process of routine optimization one would vary the levels of HPMC and ethyl cellulose with respect to the active, oxcarbazepine, with a reasonable expectation of producing a once a day tablet for delivering oxcarbazepine.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 5, the weight ratio of total HPMC to oxcarbazepine from about 1:10 to about 1:20 is would have been obvious over the weight ratio of polymer to drug from about 1:99% to about 99:1%, depending on the viscosity grade of the polymer, on the tablet dimension and shape and on the desired release rate, as taught by Katzhendler (Col. 8, lines 30-35).

Regarding instant claim 7, the weight ratio of total ethyl cellulose to oxcarbazepine from about 1:10 to about 1:20 is would have been obvious over the ratio of hydrophilic to hydrophobic polymer from about 99.9:0.1 to about 90:10 as taught by Katzhendler (Col. 9, lines 63-65). One with ordinary skill in the art would vary the level

of ethyl cellulose with respect to the HPMC and with respect to the oxcarbazepine in order to optimize the desired release rate of the active.

Regarding instant claims 10-12, the limitation of the release of oxcarbazepine as indicated in the standard in vitro dissolution tests would have been obvious over the once daily oxcarbazepine tablet composition taught by Katzhendler (Col. 11, lines 31-32). One with ordinary skill in the art would use the standard in vitro dissolution tests during the process of routine experimentation to determine the dissolution rate of oxcarbazepine over time in order to ensure that adequate levels of oxcarbazepine were released from the tablet into the dissolution medium.

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katzhendler et al. (US 6,296,873) in view of Eibl et al. (US 5,290,769).

The teaching of Katzhendler is stated above. Katzhendler teaches that the polymeric matrix of the drug delivery may also contain hydrophobic polymers such as methacrylic acid derivatives (Col. 9, lines 45-52).

Katzhendler does not expressly teach a polymethacrylates which is trimethylammonium methacrylate.

Eibl teaches tablet dosage forms (Col. 2, lines 1-2) and further teaches coating substances including copolymerizates of acrylic and methacrylic acid esters and trimethylammonium methacrylate (for example EUDRAGIT ® RL) (Col. 6, lines 23-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a sustained release tablet of oxcarbazepine with

methacrylic acid derivatives, as suggested by Katzhendler, and combine it with the copolymerizates of acrylic and methacrylic acid esters and trimethylammonium methacrylate (for example EUDRAGIT ® RL), as suggested by Eibl, with a reasonable expectation of producing a sustained release tablet of oxcarbazepine.

One with ordinary skill in the art would have done so because copolymerizates of acrylic and methacrylic acid esters and trimethylammonium methacrylate are known in the art as coating substances that are used in the production of delayed or sustained release dosage forms.

Regarding instant claim 8, the polymethacrylates which is trimethylammonium methacrylate would have been obvious over the copolymerizates of acrylic and methacrylic acid esters and trimethylammonium methacrylate, as taught by Eibl (Col. 6, lines 23-25).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 12-13 and 15-16 of copending Application No. 10/598,553 ('553 hereinafter) in view of Katzhendler et al. (US 6,296,873).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The difference is that instant claims are drawn to oxcarbazepine (10,11-Dihydro-10-oxo-5*H*-dibenz[*b,f*]azepine-5-carboxamide) and claims of '553 are drawn to 10,11-Dihydro-10-hydroxy-5*H*-dibenz[*b,f*]azepine-5-carboxamide. Katzhendler teaches oxcarbazepine and the mono hydroxy derivative (MHD) of oxcarbazepine (10,11-dihydro-10-hydroxy-5H-dibenz/b,f/azepine-5-carboxamide) as the pharmaceutical active agents (Col. 3, lines 64-65). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to make an oral, controlled release dosage form with either oxcarbazepine or the mono hydroxy derivative because both active agents are disclosed by Katzhendler.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-7 and 9-12

of copending Application No. 10/598,786 ('786 hereinafter) in view of Katzhendler et al. (US 6,296,873).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The difference is that instant claims are drawn to oxcarbazepine (10,11-Dihydro-10-oxo-5*H*-dibenz[*b,f*]azepine-5-carboxamide) and claims of '786 are drawn to 10,11-Dihydro-10-hydroxy-5*H*-dibenz[*b,f*]azepine-5-carboxamide (licarbazepine). Katzhendler teaches oxcarbazepine and the mono hydroxy derivative (MHD) of oxcarbazepine (10,11-dihydro-10-hydroxy-5H-dibenz/b,f/azepine-5-carboxamide) as the pharmaceutical active agents (Col. 3, lines 64-65). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to make an oral, controlled release dosage form with either oxcarbazepine or the mono hydroxy derivative because both active agents are disclosed by Katzhendler.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/M P WOODWARD/
Supervisory Patent Examiner, Art Unit 1615